

DOCKET NO. 9491-033-27



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: BRIAN M. FENDLY, ET AL.
SERIAL NO.: 08/948,149
FILING DATE: OCTOBER 9, 1997
FOR: ANTI-ERBB2 ANTIBODIES

ART UNIT: 1645
EXAMINER: SWARTZ, R.

Handwritten notes: "39", "JM", and "10/2/03".

RESPONSE

ASSISTANT COMMISSIONER FOR PATENTS
PO BOX 1450
ALEXANDRIA, VA 22313-1450

SIR:

This Response is submitted in answer to the Final Office Action dated February 25, 2003, which set a three month period for response. A Request for Extension of Time for two months is attached hereto and incorporated herein by reference, thereby extending the date for response from May 25, 2003 to July 25, 2003.

REMARKS

Preliminarily, Applicants wish to thank the Examiner for the courtesy of granting an interview with the Applicant's representative on May 14, 2003.

Reconsideration and allowance of the above referenced application is respectfully requested.

Claims 28-40 and 42-62 are currently pending in the application.

Claims 28-31, 37-38, 40, 56 and 57 are rejected under 35 U.S.C. §102(b) as

anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Shepard et al. (*J. Clin. Immunol.*, 11(3):117-127, 1991). Applicants respectfully traverse this rejection.

Claims 28-31, 37-38 and 40 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lewis et al. (*Cancer Immunol. Immunother.*, 37:255-263, 1993). Applicants respectfully traverse this rejection.

Claims 32-36, 39, and 58 are rejected under 35 U.S.C. §103(a) as being unpatentable over Shepard et al. (*J. Clin. Immunol.*, 11(3):117-127, 1991) or Lewis et al. (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al. (*Cancer Research*, 50:1550-1558, 1990), Deshane et al., (*J. Invest. Med.*, 43(Suppl 2):328A, 1995), and further in view of Senter et al., (U.S. Pat. No. 4,975,278). Applicants respectfully traverse this rejection.

Claims 42-55 and 59-62 are rejected under 35 U.S.C. §103(a) as being unpatentable over Shepard et al. (*J. Clin. Immunol.*, 11(3):117-127, 1991) in view of Lewis et al. (*Cancer Immunol. Immunother.*, 37:255-263, 1993) and Fendly et al. (*Cancer Research*, 50: 1550-1558, 1990) and further in view of Deshane et al. (*J. Invest. Med.*, 43(Suppl 2):328A, 1995), and Senter et al. (U.S. Pat. No. 4,975,278). Applicants respectfully traverse this rejection.

All earlier submitted arguments relating to the above rejections of the claims remain valid and, as such, are herein incorporated by reference.

Common to each of the rejections maintained by the Examiner is the contention that the primary references of Shepard et al. and Lewis et al. are prior art to the claimed invention in spite of the fact that the cited references fail to provide an enabling disclosure of the claimed antibodies. The Examiner has not argued that the references provide an enabling disclosure but instead relies on his contention that the antibodies, which are mentioned in the cited references, might be obtained from Genentech by an outside party under a Material

Transfer Agreement (MTA). This possibility is the basis for the Examiner's contention that the antibodies are publicly available. Such an over simplification disregards the stringent requirements of the Genentech MTA and the U.S. Patent Office's published position on what is required for a material to be considered available to the public. The Applicants earlier arguments directed to this issue have not been directly addressed in the present Official Action; rather the rejection has simply repeated the Examiner's contention that the antibodies of the present invention were publicly available.

In addition to all earlier submitted arguments Applicants respectfully submit the following in support of Applicants' assertion that the antibodies were not publicly available and the references cited by the Examiner as a basis for rejecting the claims do not provide an enabling disclosure and are therefore not prior art to the present invention as claimed.

Antibodies 7F3 and 7C2 are merely mentioned in Shepard (see Figure 2 on page 120) or Lewis et al. and none of the additionally cited references provide a sufficient disclosure to make up for the deficiencies of the primary cited references. As such, none of the rejections, which have been maintained by the Examiner, provide an enabling disclosure of the claimed invention. Antibodies 7F3 and 7C2 were not deposited with respect to the references and their sequences were not disclosed in the references in such a way that a skilled person could have reproduced those particular antibodies based on the references. The antibodies 7F3 and 7C2 were not publically distributed or publically available more than one year prior to October 18, 1996, the priority filing date of this application.

The Examiner's contention that the antibodies were available to the public does not properly take into account that the antibodies were only available to those researchers who first qualified to receive the antibodies and subsequently, if qualified, complied with all of the

restrictions of the Genentech Material Transfer Agreement (MTA). As argued in earlier responses and as discussed in the Examiner's Interview, the Material Transfer Agreement placed explicit restrictions on the availability and use of the antibodies. In addition, further distribution of any materials to a third party was expressly forbidden under the MTA.

As shown in the Genentech MTA and as attested to in the Declaration under 37 C.F.R. §1.132, which was submitted December 18, 2002 by Gail D. Phillips, Genentech maintained strict supervision and control over any materials requested by an outside investigator. Any such request for materials would only be considered if the research plan proposed by the outside investigator was first approved by Genentech. If the research plan was approved, the outside investigator would only be permitted access to the material if a Material Transfer Agreement was executed. The Genentech MTA gave Genentech close control and supervision over the requested materials. A Material Transfer Agreement was originally provided in an Information Disclosure Statement dated April 10, 1999. A copy of this same Material Transfer Agreement was again provided to the Examiner during the above referenced Examiner's Interview.

A study of the Material Transfer Agreement, the Declaration of Gail Phillips, and arguments, which were earlier put forth in the prosecution of the present application, consistently shows that Genentech maintained strict control and supervision of the outside investigator's experimental use of the requested materials. The control and supervision exerted by Genentech under the MTA encompassed all of the outside investigator's activity with the provided material from the required prior approval of the research plan to the required final review of the researcher's findings. In particular, the outside investigator receiving the research material under a Genentech MTA could only use the research material

for the specific research plan, which was earlier approved by Genentech. Also, the outside researcher was prohibited from disclosing or transferring the research material to any third parties. The MTA further required that the outside investigator not disclose (orally or in writing) any results of the research until Genentech had been given time to review the disclosure and make recommendations or comment upon it. Thus, 7F3 and 7C2 were not publicly available as the Examiner contends but were only made available to prior-approved outside investigators under the strict control and supervision of Genentech.

The experimental use of the materials by outside investigators, under the Genentech MTA, clearly shows that the antibodies of the present invention were not accessible to the public according to the concept of being “readily available” as described in the Manual of Patent Examining Procedure (MPEP) and relevant case law. With regard to the public accessibility to biological material, the MPEP states:

...biological material is accessible because it is known and readily available to the public. The concepts of “known and readily available” are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. To avoid the need for a deposit on this basis, the biological material must be both known and readily available - neither concept alone is sufficient. (Emphasis added)

MPEP, p. 2404.01

As stated in the excerpt from the MPEP, directly above, the level of public accessibility that is considered to be “readily available” is consistent with “an ability to make and use the invention” (that is, to render the disclosure enabling). Absent that level of accessibility the enablement requirement cannot be met.

Biological materials, which are placed in a depository, in comparison to those materials that are privately retained, are generally expected to be available to the public.

However, even for materials that are deposited, the U.S. Patent and Trademark Office recognizes instances when the materials are not readily available to the public. The MPEP, in discussing the ready availability of biological materials states:

... If a deposit is not made under the conditions set forth in 37 CFR § 1.808(a), the deposit cannot be relied upon for other purposes, e.g., the deposit cannot be relied upon by a third party to establish “known” and “readily available” in another application. (Emphasis added)

MPEP (*id.*)

Furthermore, the MPEP, in addressing materials that are placed in a depository recognizes that limitations that are placed on access to those materials can render the materials not “readily available.” On such limitations the MPEP states:

... Once a deposit is made in a depository complying with these rules, and under conditions complying with these rules, a biological material will be considered to be **readily available** even though some requirement of law or regulation in the United States or in the country where the depository institution is located permit access to the material only under conditions imposed for health, safety or similar reasons. This provision is consistent with the Budapest Treaty (Article 5) and is designed to permit the patenting of inventions involving materials having restricted distribution, where the restrictions are imposed for the public, as opposed to the private, welfare.

MPEP (*id.*)

The restrictions which are imposed by the Genentech MTA are required solely for the “private welfare” of Genentech, Inc. and are protective of Genentech’s proprietary interest in maintaining strict supervision and control over the antibodies at issue. That being the case, the antibodies would not be considered “readily available” under the requirements of the MPEP and relevant case law.

Experimental use and testing of materials has long been permitted without such use being considered as making the material readily available to the public or being of public use. While the experimental use is personal to an applicant, it has been long been recognized by

the U.S. Patent Office and by the Courts that the involvement of a third party in the experimental use of an invention is permissible. In specifically addressing the long-established allowance for experimental testing of inventions where such testing was done by an outside party, the MPEP states:

The statutory bars of 35 U.S.C. 102(b) are applicable even though public use or on sale activity is by a party other than an applicant. Where an applicant presents evidence of experimental activity by such other party, the evidence will not overcome the prima facie case under 35 U.S.C. 102(b) based upon the activity of such party **unless the activity was under the supervision and control of the applicant.** *Magnetics v. Arnold Eng'g Co.*, 438 F.2d 72, 74, 168 USPQ 392, 394 (7th Cir. 1971), *Bourne v. Jones*, 114 F.Supp. 413, 419, 98 USPQ 206, 210 (S.D. Fla. 1951), *aff'd.*, 207 F.2d 173, 98 USPQ 205 (5th Cir. 1953), cert. Denied, 346 U.S. 897, 99 USPQ 490 (1953); contra, *Watson v. Allen*, 254 F.2d 342, 117 USPQ 68 (D.C. Cir. 1957).

MPEP 2133.03(e)(7)

As indicated directly above, the MPEP and relevant case law has recognized that, if the experimental use of an invention by an outside party is to be considered a permissible use, it is important that the inventor maintain supervision and control over the materials of the invention. Importantly, participation of an outside party in such experimental activity is not prohibited; but, rather is a recognized and acceptable experimental use of the invention if such use (and therefore necessarily knowledge) of the invention is under the supervision and control of the inventor. On this issue, the MPEP further states:

As discussed with reference to *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1878), a significant determinative factor in questions of experimental purpose is the extent of supervision and control maintained by an inventor over an invention during an alleged period of experimentation. Once a period of experimental activity has ended and supervision and control has been relinquished by an inventor without any restraints on subsequent use of an invention, an unrestricted subsequent use of the invention is a 35 U.S.C. § 102(b) bar. *In re Blaisdell*, 242 F.2d 779, 784, 113 USPQ 289, 293 (CCPA 1957).

MPEP 2133.03.03(e)(5)

As discussed above, a study of the Genentech MTA and the Declaration of Gail Phillips clearly shows that the extent of Genentech's supervision and control over the use of any material provided to an outside investigator under the Genentech MTA would have been absolute. Indeed, as earlier stated, an outside investigator requesting material from Genentech would preliminarily have to submit a research plan for approval before Genentech would have considered granting the materials. As stated in the Declaration of Gail Phillips, if the research plan was approved, then the outside investigator would have been required to execute the Genentech MTA prior to receiving the requested materials. The provided materials could only be used in accordance with the prior approved research plan and, further, it was required that the results of their experiments had to be submitted to Genentech for recommendations and comments. Importantly, the outside investigator was prohibited from disclosing or providing the materials to any third party. Thus, the policies of Genentech as reflected in the Declaration of Gail Phillips and as delineated in the Genentech MTA served to maintain complete control and supervision over any materials provided to an outside investigator. This level of control and supervision is completely consistent with the requirements for control and supervision expressed in the MPEP and relevant case law. An outside investigator operating under the Genentech MTA would have no freedom whatsoever to use the provided materials outside of the restrictions of the MTA or to disclose or distribute those materials to a third party.

In view of the earlier submitted arguments, which are incorporated herein by reference, and the above remarks, Applicants respectfully submit that the antibodies of the present invention were not readily available to the public and the primary references of Shepard et al. and Lewis et al., upon which the present rejections of the claims rely, do not

provide an enabling disclosure of the antibodies of the present invention. As such, they are not proper prior art references against the invention as claimed. Accordingly, withdrawal of the present rejections under 35 U.S.C. § 102(b) and § 103(a) is respectfully requested.

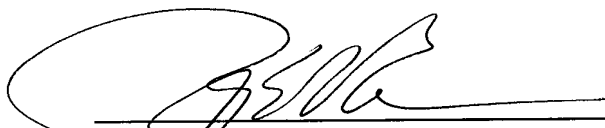
CONCLUSION

In light of the above, Applicants believe that this application is now in condition for allowance and therefore requests early and favorable consideration.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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